

REMARKS

Claims 1-22 are pending. No new matter has been added by way of the present amendment. For instance, claims 1 and 6-10 have been amended to remove the phrase "preparation comprising." Claims 1, 8, 9 and 10 have also been amended to recite the specific result as current recited in the preamble of these claims. New claims 17-22 are supported by the present specification at page 4, line 25 to page 5, line 2 and page 5, lines 10-15. Accordingly, no new matter has been added.

In view of the following remarks Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues Under 35 U.S.C. §103(a)

The Examiner has rejected claims 1-16 under 35 U.S.C. §103(a) as being obvious over Kosbab, United States Publication US 2001/0031744 A1 (hereinafter referred to as Kosbab) in view of Hartung, USP 4,163,067 (hereinafter referred to as Hartung) and Hadhanyi, USP 3,953,423 (hereinafter referred to as Hadhanyi). Applicants respectfully traverse this rejection.

Kosbab discloses a completely water soluble extract of licorice. As acknowledged by the Examiner, the present claims differ from Kosbab in that the licorice extract of Kosbab is not water-insoluble and glycyrrhizinic acid free. However, these

are not the only distinctions which exist. In addition, Kosbab fails to suggest or disclose ethanolic extracts, or ethanol soluble extracts of licorice.

The citation of Hadhanyi relates to a slightly water soluble extract of licorice and the citation of Hartung relates to an extract that is water insoluble. Based upon these disclosures the Examiner asserts that "it would have been obvious ... to replace the licorice extract disclosed by Kosbab with the licorice extract disclosed by Hartung, because licorice extracts with the glycyrrhizinic acid removed and prepared as an ethanolic extract as further disclosed by Hadhanyi find medicinal uses in the art" and because "the art clearly recognizes that the presence of the [glycyrrhizinic] acid causes health problems". Applicants disagree.

The cited art relates to three different extraction products of Licorice:

- A completely water soluble extract (and known for 3000 years, mentioned by Kosbab);
- An extract that is slightly soluble in water, prepared by Hadhanyi from water-soluble extract (see Col. 1 lines 58-61), and described by him as having medicinal effect; and
- An extract that is water insoluble (prepared by Hartung from water-insoluble portion of the licorice root (see Claim 1)), and not described by him to have any medicinal use.

The three extracts, related to in these three references, are indeed of similar origin, but they are different in their chemical components as well as in their expected medicinal potency. Furthermore, none of the references either in combination or individually disclose a licorice extract that is water insoluble, free from glycyrrhizinic acid, and having the specific uses currently claimed. Rather, the Examiner must pick and choose between the references to arrive near the presently claimed subject matter. As such, Applicants submit that one of ordinary skill in the art would not be motivated to combine these references as suggested by the Examiner. That is, when the prior art is taken as a whole, one of ordinary skill in the art would have no motivation to arrive at the currently claimed invention. Thus, the Examiner has failed to present a valid *prima facie* case of obviousness. Applicants will discuss this further below.

Applicants submit it is not obvious to replace the licorice extract of Kosbab with that of Hartung, since the Hartung extract is not described to have any medicinal use. The Hadhanyi extract is described to have medicinal use, but not one that obviates its replacement with the extract mentioned by Kosbab. Kosbab uses the licorice extract because, as mentioned in paragraph [0361] thereof, it is believed that it "can function for neovascular regulation" (i.e. to regulate formation of blood vessels). Nothing in Hadhanyi shows that the licorice extract disclosed therein has

this ability, and therefore, it is not at all obvious to replace Kosbab's licorice extract with that of Hadhanyi.

Kosbab also teaches against using a licorice extract for treating cardiovascular diseases, diabetes, and hypertension (all claimed in the present application), since each of these disorders are treated by Kosbab with a series of other substances (see tables 1 and 2 in Kosbab). Presumably, had Kosbab intended licorice extract to treat such disorders, he would have mentioned this in the publication.

The extract of Hadhanyi is water soluble (even if only slightly) and not very soluble in ethanol (see column 4 lines 61-64). Therefore, its combination with Kosbab (or standing on its own) cannot suggest the claimed invention, since the licorice extract is different from the one claimed. The Hadhanyi extract is not water insoluble as recited in the claims. The claims relating to ethanolic extract of licorice are even further from the prior art, since it is clear that an ethanolic extract is ethanol soluble, while that of the prior art is not. The Examiner is referred to claims 11-22.

Moreover, the Examiner suggested modification of Kosbab, having an effective filing date of approximately 1997, runs against common sense. Both the Hadhanyi and Hartung references, having issue dates of 1979 and 1976, respectively, were available to Kosbab. Accordingly, if the modifications suggested by the

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Examiner were so obvious, why did Kosbab himself not make use of the references as suggested by the Examiner?


In summary, Applicants submit that the Examiner has failed to present a valid *prima facie* case of obviousness. Accordingly, the Examiner is respectfully requested to withdraw all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

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